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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,672	06/01/2001	Ryota Sugimoto	018961-054	8651
39083	7590	01/25/2005	EXAMINER	
CERMAK & KENEALY, LLP			MATHEW, FENN C	
23 W. Myrtle St			ART UNIT	
Alexandria, VA 22301			PAPER NUMBER	
			3764	
DATE MAILED: 01/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/870,672	<b>Applicant(s)</b> SUGIMOTO, RYOTA	
	<b>Examiner</b> Fenn C Mathew	<b>Art Unit</b> 3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,5,9-20,22,23 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9-20,22,23 and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/08/2004 has been entered.

### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 4, 5, 9-13, 20, 22-23, 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley (U.S. 6,293,967) and further in view of Palmaz (WO99/23977). Shanley discloses an implantable tubular device formed substantially tubular including wavy annular members arranged in an axial direction of the device with bent portions (118, 122). Shanley fails to teach deformable portions in the form of grooves as claimed by the Applicant, however, Palmaz teaches an analogous device and teaches that it is desirable to have grooves with a V-shaped bottom on the stent, inherently defining deformable portions. Furthermore, Palmaz discloses that it is desirable to have deformable portions at any portion of the stent. Therefore, as it would have been obvious to one having ordinary skill in the art at the time of invention to

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provide the stent, including the wavy annular portions and free bent portions of Shanley with grooves as taught by Palmaz in order to aid in migration of cells. Palmaz further teaches on page 8, in the first full paragraph that a variety of different groove patterns may be utilized including a diagonal pattern as seen in figure 8 that would inherently result in a spiral-like formation upon expansion, as well as grooves perpendicular to the axial direction which would result in an annular configuration. The modified Shanley fails to disclose the specific depth of the grooves as a percentage of the thickness of the device, however, the claimed range would be obvious to one of ordinary skill in the art, especially in light of figures 9 and 12 which would suggest that the depth ratio is approximately in the claimed range. The modified Shanley teaches that the deformable portions form an angle between 20-90 degrees with the axial direction of the device. The modified Shanley also teaches as mentioned above that the grooves may be placed anywhere and at any interval, therefore, the specific interval chosen would be considered a matter of obvious design choice, as the claimed range would perform equally well absent unexpected or undesired results. The modified Shanley consists of a stent having a frame structure. The modified Shanley further teaches the grooves on an inner surface of the stent.

4. With respect to claims 11-12, the claims are product by process claims. As such, the process by which the device is formed is not germane to the patentability of the device itself. The feature of annular or spiral deformable portions has been addressed above.

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5. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shanley in view of Palmaz as applied to claim 1 above, and further in view of Alt et al. (U.S. 5,788,979). The modified Shanley discloses the claimed invention except for the device carrying a medicine. Alt teaches that it is well known and advantageous to provide a medicinal coating to stents (column 8). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the modified Shanley with a medicinal coating as taught by Alt in order to deliver medicine to areas of the body once the device has been implanted. Alt further teaches a coating comprising a biodegradable material (column. 6, lines 59-64), which can be used for a stent (col. 6, line 1). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the device including the deformable portions disclosed by the modified Shanley with the coating taught by Alt in order to provide a more biocompatible implant that will not cause harm during degradation. Alt further teaches that the coating has the medicine added to it, and that the medicine can consist of an antibiotic.

### ***Response to Arguments***

6. Applicant's arguments filed 11/08/2004 have been fully considered but they are not persuasive. Palmaz reasonably describes different configurations with respect to the manner in which the grooves are arranged on the body of the stent, including straight across perpendicular to the axial direction, which would reasonably result in an annular ring as claimed by the applicant, as well as a configuration suggesting a spiral 'deformable portion' on the basis of a diagonally formed groove transecting different

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parts of the stent. One of ordinary skill in the art need look no further than the cited sections above to come to claimed device, absent Applicant's own disclosure. With respect to the claimed ranges being a matter of obviousness to one of ordinary skill in the art, the disclosure of Palmaz suggests a variety of groove depths as well as distances between deformable portions, not to mention placing the grooves at any portion of the stent thereby lending credence to the argument that the skilled artisan would have found it obvious to place grooves on the bent portion of a stent absent unexpected or undesired results.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (571) 272-4978. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*fcm*

fcm

January 14, 2005

*JY*

JUSTINE R. YU  
SUPERVISORY PATENT EXAMINER  
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*1/21/05*